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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,152	12/27/2000	Peter Watts	10774-21U1	5106

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	20

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/749,152	Applicant(s) WATTS, PETER	
	Examiner Susan Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Request for Reconsideration filed 12/23/02, Supplemental Request for Reconsideration and Terminal Disclaimer filed 01/31/03.

Terminal Disclaimer

The terminal disclaimer filed on 01/31/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,228,396 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Rashid et al. WO 94/09745.

Rashid teaches a controlled release capsule comprising starch capsule coated with a solution of polyvinyl chloride or a polyvinyl acetate copolymer, or an ethyl cellulose solution (page 7, 1st paragraph). Rashid further teaches the capsule is filled with pharmaceutical active agent, and after 2 to 10 hours of administration, the active agent is released into the patient's gastro-intestinal tract (pages 10-11).

Claims 1, 2, 5-7, 9, 10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dansereau et al. US 5,622,721.

Dansereau teaches an enteric-coated oral dosage form, wherein the release of active agent is to the lower gastrointestinal tract (see abstract, column 2, lines 50-65). The dosage form can be an enteric-coated starch or gelatin capsule (column 6, lines 52 through column 7, lines 1-10). The coating includes, polymer or copolymer that dissolves at a pH of 5.5 or above, *e.g.*, Eudragit®, or methacrylic acid polymer-copolymer (columns 9-10).

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kelm et al. US 5,656,290.

Kelm teaches pharmaceutical dosage form for colonic delivery comprising drug encapsulated in hard capsule with coating layers, which begins to dissolve at a pH of above 5 (columns 3-4). The hard capsule can be starch or gelatin capsule, and the coating can be copolymer of methacrylic acid and methyl methacrylate, and cellulose derivatives (columns 9-11). The coating thickness is about 110 to 350 μm (columns 12-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 5,670,158, and McNeil et al. US 5,342,624.

Davis teaches pharmaceutical dosage form for colonic delivery comprising drug encapsulated in an enteric-coated capsule (column 6, lines 27-48). The enteric coating comprises pH sensitive material that will dissolve at a pH of above 5, *e.g.*, polymethacrylates (column 9, lines 1-11). Davis does not teach the claimed starch capsule.

McNeill teaches hard gelatin capsule or starch capsule are conventional class of capsules. Hence, it is the examiner's position that gelatin capsule and starch capsule are substantially equivalent, and therefore, it would have been obvious for one of

ordinary skill in the art to modify Davis' capsule using the starch capsule, because the references teach the advantageous results in the use of a controlled release device useful to deliver drug to the colon. The expected result would be an enteric-coated starch capsule suitable for colonic delivery to treat colonic diseases

The examiner notes that the references do not teach the coating thickness as defined in claim 8. However, Davis teaches the thickness of the coating depends in the desired rate of dissolution and the site of release. Therefore, it is the position of the examiner that it would have been obvious to one skilled in the art to manipulate the coating thickness similar to that of the claimed coating thickness, because the references also desired to release the active agent in the colon.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 5,670,158, in view of Digenis et al. US 5,672,359.

Davis is relied upon for the reason stated above. Davis does not teach the claimed starch capsule.

Digenis teaches coated hard gelatin capsule made from gelatin or starch or hydrophilic polymer suitable for colonic delivery of peptide drugs (column 4, lines 20-67, column 8, lines 50-57, and examples). Examples of peptide drugs are vaccines and proteins (column 8, lines 58-67). Thus, it would have been obvious for one of ordinary skill in the art to optimize Davis' capsule using the starch capsule in view of the teaching of Digenis, since Digenis teaches that hard gelatin capsule can be gelatin or starch or hydrophilic. The expected result would be a coated capsule useful for colonic delivery.

Claims 2-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rashid et al. WO 94/09746, in view of Dansereau et al. US 5,622,721.

Rashid is relied upon for the reason stated above. Rashid does not teach the claimed coating materials.

Dansereau teaches an enteric-coated oral dosage form, wherein the release of active agent is to the lower gastrointestinal tract (see abstract, column 2, lines 50-65). The dosage form can be an enteric-coated starch or gelatin capsule (column 6, lines 52 through column 7, lines 1-10). The coating includes, polymer or copolymer that dissolves at a pH of 5.5 or above, *e.g.*, Eudragit®, or methacrylic acid polymer-copolymer (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to optimize the coating of Rashid using the coating materials in view of the teachings of Dansereau, because the references recognize the advantageous results in the use of delay coating materials suitable to coat starch capsule to release active agent in the intestinal tract.

The examiner notes that the references do not teach the coating thickness as claimed in claim 8. However, Dansereau teaches the coating also achieves the delivery to the active to the lower gastrointestinal tract at a point which can be manipulated by one skilled in the art by choosing the excipients which make up the coating, its type, and/or its thickness. Accordingly, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation determines a suitable thickness for the coating to obtain a desirable release of active agent in a colon.

Response to Arguments

Applicant's arguments filed 12/23/02 have been fully considered but they are not persuasive.

Applicant argues that applicant agrees to the election of a single species for prosecution on the merits that is a vaccine with the understanding that the Examiner will examine the generic claim 1 with respect to the elected species as set forth above, and upon finding such subject matter allowable, the Examiner will examine the claims directed to each of the non-elected species until all have been found to be allowable. Contrary to the applicant's argument, a restriction and/or election of species have never been issued from the Office. Claims 14-17 have been withdrawn from consideration as being directed to an invention non-elected by original presentation, and therefore, will not be examined.

Applicant states in the Remarks, at page 3, "as threshold matter, the applicant notes that it is not precisely clear whether the Examiner is applying Kelm '290 or Kelm '106 in her underlying reasoning for this 103(a) rejection...applicant has assumed that the Kelm reference referred to in this rejection is Kelm '290...If the applicant's assumption is correct, he requests that the Examiner expressly state which Kelm reference she is relying upon, and not make such rejection final". In response to the applicant's request, the Examiner has not been able to determine where the Kelm '106 comes from? As noted by the Examiner, the entire Office Action dated 08/19/02, never cited Kelm '106 in the rejections. The parents of Kelm '290 have been ordered, but

have not yet arrived. Until then, the examiner maintains the 103(a) rejections over Kelm '290, and this Office Action is made non-final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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